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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/763,499      | 08/27/2001  | Namita Surolia       | IN99/00026          | 8616             |

7590                    08/22/2003

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EXAMINER

WEDDINGTON, KEVIN E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/22/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |                 |
|------------------------------|-----------------|-----------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)    |
|                              | 09/763,499      | SUROLIA, NAMITA |
| Examiner                     | Art Unit        |                 |
| Kevin E. Weddington          | 1614            |                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 May 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 7-35 is/are pending in the application.
- 4a) Of the above claim(s) 17, 18 and 21-35 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 7-16, 19 and 20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

|  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

Claims 7-35 are presented for examination.

Applicant's preliminary amendment filed February 23, 2001 has been received and entered.

Applicant's election filed May 27, 2003 in response to the restriction requirement of March 5, 2003 has been received and entered. The applicant elected the invention described in claims 7-13, 15, 16, 19 and 20 (Group I) with traverse. Claim 14 will be examined with Group I, thus examining claims 7-16, 19 and 20.

Applicant's traverse of the restriction requirement for the remaining claims is not found persuasive for reasons set forth in the previous Office action. The restriction requirement is hereby made Final.

Claims 17, 18 and 21-35 are withdrawn from consideration as being drawn to the non-elected invention. (37 CFR 1.142(b))

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-13, 15, 16, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9-13, 15 and 16 are rendered indefinite because the claims depend upon cancelled claim 1. Claims 19 and 20 are rendered indefinite because they depend upon claim 10 ( a rejected claim).

Regarding claim 14, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gump (A), and Model et al. (B).

Gump teaches dihydroxy hexachloro diphenyl methane compounds effective against micro-organisms.

Model et al. teach halogenated hydroxy-diphenyl ethers and esters thereof are useful in bactericidal compositions. The halogenated hydroxy-diphenyl ethers and esters include the applicant's preferred compound, triclosan.

The applicant's is claiming a composition comprising an inhibitor of fatty acid synthesis (hydroxydiphenyl ethers) which reads on the compounds per se and it does not matter how the composition is used, for example, an antibacterial composition comprising triclosan; is the same as an antimalarial composition or a paint composition comprising triclosan or other hydroxydiphenyl ethers. Applicant is not entitled to procure claims based on discovery that well-known and old compounds can be adapted to new uses; to entitle him to a patent, the compounds must be both new and unobvious to one skilled in the art. (See In re Hack 114 USPQ 161).

Claims 7-14 are not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gump (A) and Model et al. (B).

The two cited references were discussed above supra for its use of a composition comprising hydroxydiphenyl ether compounds.

The instant invention differs from the cited reference in the cited reference does not teach the applicant's preferred dosage range of claim 15. However, the determination of a dosage range having optimum therapeutic index is well within the level of one having ordinary skill in the art, and the artisan would have been motivated to determine optimum dosage amounts to get the maximum effect of the composition.

Claim 15 is not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (703) 308-4650. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703)308-1235. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

K. Weddington  
August 15, 2003

  
*Kevin E. Weddington*  
Primary Examiner  
Art Unit 1614